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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,129	06/28/2000	Mahin D. Maines	176/60792(6-11415-868)	5529

7590 02/25/2005

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EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/606,129	<b>Applicant(s)</b> MAINES, MAHIN D.	
	<b>Examiner</b> Delia M. Ramirez	<b>Art Unit</b> 1652	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 18 January 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): see attached.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: 76.  
 Claim(s) rejected: 68, 71-75, 77.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

### ADVISORY ACTION

1. Claims 68, 71-77 are pending.

2. The request for entering amendments to claims 68, 73, 77, submission of a declaration by inventor Mahin Maines under CFR 1.132, and arguments filed on 1/18/2005 under 37 CFR 1.116 in reply to the Final Action mailed on 7/14/2004 are acknowledged. The proposed amendments to the claims will be entered. The amendments are deemed sufficient to overcome the 35 USC 112, first paragraph new matter rejection of claims 68, 71-76, and some of the grounds of rejection previously applied in regard to 35 USC 112, first paragraph written description and scope of enablement. However, the amendments are not deemed sufficient to overcome the 35 USC 112, first paragraph rejections previously applied for the following reasons.

3. Claims 68, 71-75 and 77 would remain rejected under 35 USC 112, first paragraph as failing to comply with the enablement requirement in view of the fact that the claims still encompass practicing the claimed method *in vivo* and encompass a method which would result in a treatment to be effected. Applicants have submitted a declaration by inventor Maines in support of the argument that the *in vitro* results obtained are predictive of *in vivo* success. The Examiner has fully considered the declaration and the experimental results submitted with the declaration. While the transfection of 293 cells *in vitro* provides useful information as to the possibility of transfecting isolated human cells with the pCDNA3 vector, this is not deemed sufficient for one of skill in the art to reasonably conclude that one could practice the claimed method *in vivo*. To practice the claimed method *in vivo*, delivery of the nucleic acid encoding the BVR is required to the target cell. However, the art teaches the difficulties associated with delivery of genes to the target cell and sustained expression after transformation. Thus, delivery of the BVR nucleic acid *in vivo* and achieving sustained expression is not considered routine experimentation. In addition, the claimed invention requires not only being able to transform a mammalian host cell *in vivo*

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with but it also requires that the expression of the nucleic acid encoding the BVR would result in regulation of protein kinase C *in vivo*. Thus, even if one were to assume that the *in vitro* experimental results provided in the declaration support the argument that delivery of the BVR nucleic acid to the target cells *in vivo* can be achieved without undue experimentation, the method still requires sustained expression of said nucleic acid *in vivo*, which as known in the art is unpredictable. Furthermore, as previously discussed, the art teaches that there are major differences between the *in vitro* and *in vivo* environments, particularly the high complexity and cell-cell interactions present in the *in vivo* environment. In the instant case, PKCs are involved in cell-surface signal transduction and their activity is highly regulated by the many interactions among different cells and interactions between the cells and the environment. As such, *in vitro* results cannot be used to extrapolate *in vivo* results.

4. Claims 68, 71-75 and 77 would be allowable if limited to *in vitro*.

5. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: NONE

Claims(s) objected to: 76

Claim(s) rejected: 68, 71-75, 77

Claim(s) withdrawn from consideration: NONE

6. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from

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either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
February 18, 2005

  
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